

Attorney Docket No. P70555US0
Application No. 10/532,348

Remarks/Arguments:

Claims 1 and 2 are pending.

Claims 1 and 2 are amended, hereby, merely to better effect formalities in accordance with PTO Rules. The amended claims define the identical subject matter defined in the original claims.

Present claims 1 and 2 stand rejected under 35 USC 102(b) as allegedly anticipated by GB 2360845 ("Ghoos"). Reconsideration is requested.

For anticipation under § 102 to exist, each and every claim limitation, as arranged in the claim, must be found in a single prior art reference. *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 USPQ 253 (Fed. Cir. 1985). The "absence" from a prior art reference of a single claim limitation "negates anticipation." *Kolster Speedsteel A B v. Crucible Inc.*, 230 USPQ 81, 84 (Fed. Cir. 1986). A reference that discloses "substantially the same invention" is not an anticipation. *Jamesbury Corp.* To anticipate the claim, each claim limitation must "*identically* appear" in the reference disclosure. *Gechter v. Davidson*, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997) (*emphasis added*). To be novelty defeating, a reference must put the public in possession of the identical invention claimed. *In re Donahue*, 226 USPQ 619 (Fed. Cir. 1985).

The presently claimed invention provides a "method for determining . . . gastric emptying," limited to, *i.e.*, "wherein body-related conversion factors are dispensed with." According to the statement of rejection, Ghoos fully meets all limitations on the rejected claims, including the limitation "where body-related conversion factors are dispensed with" (Office Action, page 2, last two lines). With all due respect, the statement of rejection is mistaken.

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Ghoos discloses a method for measuring gastric emptying, as alleged in the statement of rejection. However, contrary to the statement of rejection, the (negative) limitation on the present claims "wherein body-related conversion factors are dispensed with" is absent from the teachings of the cited reference.

As taught by Ghoos (page 6, paragraph immediately following heading "*Analysis of the tubes*") (emphasis added):

¹³C contents in breath is [*sic*] determined by on line gas chromatographic purification-isotope ratio mass spectrometry (ABCA: Europe Scientific). The δ value given by the isotope ratio mass spectrometry are [*sic*] converted to percentage ¹³C recovery of the initial amount administered per hour (% dose ¹³C/h) according to the calculations described in detail by Ghoos et al (5)[.]

As such, measuring the amount of ¹³C in air exhaled by the test subject is determined from a value " δ "—obtained by subjecting the exhaled air to isotope ratio mass spectrometry—which value is then "converted . . . according to calculations" using the % dose ¹³C per hour administered to the body of the test subject.

In other words, body-related conversion—of the " δ " value obtained using isotope ratio mass spectrometry—to a percentage ¹³C recovery value is taken into account, i.e., "body-related conversion factors" are not "dispensed with" in the Ghoos method (as opposed to the presently claimed method), allegations to the contrary in the statement of the rejection, notwithstanding.

The conversion is calculation employed by Ghoos was for the purpose of conforming the breath test (results) with "radioscintigraphy" (Ghoos, page 7, paragraph immediately following

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heading "*In conclusion*"). *Radioscintigraphy* was considered to be "correct," i.e., to be the *gold standard*, as disclosed in the instant specification (pages 1 and 2).

To correlate radioscintigraphy with breath tests, body-related factors were used to calculate gastric half-emptying time and log phase. On the other hand, applicant discovered that the breath test—as presently claimed—is superior to radioscintigraphy; and, therefore, no body-related factors are to be used to calculate the results.

Accordingly, the "absence" from *Ghoos* of the limitation "wherein body-related conversion factors are dispensed with" on the present claims "negates anticipation" of the present claims by the cited reference. *Kolster Speedsteel A B*, 230 USPQ at 84. To anticipate the claim, each claim limitation must "identically appear" in the reference disclosure. *Gechter*, 43 USPQ2d at 1032.

For the foregoing reasons, the rejection of present claims 1 and 2 under § 102 (b) as allegedly anticipated by *Ghoos* is overcome. Withdrawal of the rejection appears to be in order.

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Favorable action is requested.

Respectfully submitted,



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